

JUL 1 0 2001

510(K) SUMMARY
(as required by 807.92(c))

K 01/205

Submitter of 510(k):

ISOAID
7824 Clark Moody Blvd.
Port Richey, FL 34668

Phone: 727-815-3262
Fax: 727-815-1972

Contact Person:

Max Taghizadeh

Date of Summary:

April 5, 2001

Trade Name:

ISOAID Iodine Brachytherapy Seeds

Classification:

Class II, Classification number is 90 KXX

Classification Name:

Brachytherapy, Radionuclide

Predicate Device:

Prostec 125I Brachytherapy Seeds – K993280

**Device Description/
Comparison:**

The ISOAID iodine-125 seeds are cylindrical sealed sources of iodine 125. The outer capsule of the source is sealed titanium. The specifications for the ISOAID device are the same as for the predicate.

Comparison Chart

	Isoaid Brachytherapy Seeds	Prostec 125 I Brachytherapy Seed
510(k) Number	To Be Determined	K993280
Indications for Use	Brachytherapy for localized tumors	Same
Capsule	Titanium	Same
Capsule Sealing Method	Laser Weld	Same
Half-Life	59.4 Days	Same
Length	4.5 mm	Same
Outside Diameter	0.8	Same
Application Method	Through an 18 gauge Needle	Same
Apparent Activity	0.10 to 5.0 mCi	0.1 to 5.0 mCi

Intended Use:

The ISOAID Iodine Brachytherapy Seeds is intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 1 0 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ISOAID
% Mr. Art Ward
Medical Device Consultant
RMS
962 Allegro Lane
APOLLO BEACH FL 33572

Re: K011205
ISOAID Iodine Brachytherapy Seeds, Model Advantage I-125
Dated: April 5, 2001
Received: April 19, 2001
Regulatory Class: II
21 CFR 892.5730/Procode: 90 KXX

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K011205

Device Name:

Indications For Use:

The ISOAID Iodine Brachytherapy Seed is intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

David A. Syron
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011205